DLA Piper LLP (US)
1251 Avenue of the Americas
27th Floor
New York, New York 10020-1104
www.dlapiper.com

Loren H. Brown
loren.brown@us.dlapiper.com
T 212.335.4846
F 212.884.8546

December 16, 2024

Via ECF
Hon. Katherine Polk Failla
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

MEMO ENDORSED

Re: *In re: Chantix (Varenicline) Mktg., Sales Practices and Prods. Liab. Litig. (No. II)*, 22-MD-3050 (KPF), 22-mc-3050 (KPF) (S.D.N.Y.)

Dear Judge Failla:

Defendant Pfizer Inc. ("Pfizer") writes in response to Plaintiffs' letter of December 11, 2024 (ECF No. 73). As discussed below, the Court should deny Plaintiffs' request because: (1) it is premature under Federal Rule of Civil Procedure 26(d)(1) and improper under Your Honor's Individual Rules of Practice in Civil Cases, and (2) documents Pfizer has produced already show that Plaintiffs' remaining claims are preempted. If the parties conduct any discovery at all at this stage, rather than proceed with Plaintiffs' wide-ranging and largely irrelevant discovery, the parties should focus on the evidence relevant to the preemption issue first, before they spend significant time and resources developing claims that are not viable.

First, Plaintiffs' discovery request is premature because the Court's stay of discovery remains in effect, a scheduling order has not been entered, and the parties have not held a Rule 26(f) conference. *See* Fed. R. Civ. P. 26(d)(1) ("A party may not seek discovery from any source before the parties have conferred as required by Rule 26(f), except in a proceeding exempted from initial disclosure under Rule 26(a)(1)(B), or when authorized by these rules, by stipulation, or by court order."). "[Rule] 26(d)(1) forbids a party from seeking discovery 'from any source before the parties have conferred as required by Rule 26(f)' except as 'authorized . . . by court order.'" *In re BitTorrent Adult Film Copyright Infringement Cases*, 296 F.R.D. 80, 86 (E.D.N.Y. 2012), *report and recommendation adopted sub nom. Patrick Collins, Inc. v. Doe 1*, 288 F.R.D. 233 (E.D.N.Y. 2012) (citing Fed. R. Civ. P. 26(d)(1)). "This is generally viewed as requiring a showing of good cause." *Id.* (citing *Ayyash v. Bank Al–Madina*, 233 F.R.D. 325, 326 (S.D.N.Y. 2005)).

The Court granted a stay of discovery on April 17, 2023 (ECF No. 35) while it considered Pfizer's Motion to Dismiss, which was subsequently filed on June 20, 2023 (*see* ECF No. 42). On May 28, 2024, the Court granted in part and denied in part Pfizer's Motion and ordered supplemental briefing (ECF No. 58). At no point did the Court indicate that the stay of discovery had been lifted, given the pendency of the supplemental briefing on the Motion to Dismiss. Nonetheless, on June 18, 2024, Plaintiffs served interrogatories and ***110 requests for production*** without first seeking leave of the Court and demonstrating good cause, even though the stay

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remained in effect, supplemental briefing on Pfizer's Motion to Dismiss was ongoing, no scheduling order had been entered, and no Rule 26(f) conference had occurred. As such, Plaintiffs' discovery requests are premature and not permitted. Therefore, Pfizer was not obligated to respond.

Moreover, Plaintiffs' requested relief is improper under Your Honor's Individual Rules of Practice in Civil Cases. Plaintiffs request that "the Court . . . ***direct Pfizer to confer*** with Plaintiffs to finalize document custodians and search terms, and to begin rolling productions of responsive documents and information by January 6, 2025" (ECF No. 73). However, the relief available under § 2(C)(ii) is an informal conference with the Court, not a conference among the parties.

Even though discovery had not commenced, Pfizer cooperated and served responses and objections to Plaintiffs' 110 requests for production and produced non-custodian documents addressing the nitrosamine issue. In subsequent meet and confers, Pfizer identified for Plaintiffs specific examples of how their requests lacked relevance, were overbroad, and were not proportional to the needs of the case. (*See* Exhibit A.) Notwithstanding the procedural posture of the case, Pfizer also agreed to produce the New Drug Application ("NDA") and regulatory file (*i.e.*, all communications with FDA) for Chantix. (*Id.*) Pfizer expects to produce the first set of those documents—which will total approximately 660,000 pages—on or before December 30.

Second, even if Plaintiffs' discovery requests were permissible now (which they are not), the documents Pfizer already has produced show that Plaintiffs' remaining claims are preempted. In the Court's ruling on Pfizer's motion to dismiss, it held that Plaintiffs' claims relating to Pfizer's alleged "Sameness Misstatement" and "Active Ingredient Misstatement" were preempted, and that only Plaintiffs' claims predicated on Pfizer's alleged "cGMP Misstatement" were not preempted. (ECF No. 58 at 32-53.) The Court held that only two cGMP claims—Pfizer's alleged lack of a quality control unit and written procedures for production and process controls—were specific enough to avoid preemption. (*Id.* at 53-54.) And the Court specifically noted that "[a] different conclusion might lie . . . after discovery in this matter, when Defendant has had the opportunity to adduce a more robust record supporting its compliance with both cGMPs." (*Id.* at 54.)

As Pfizer explained to Plaintiffs in a meet and confer on November 5, the documents Pfizer already produced show that the source of the nitrosamine at issue is an excipient, an inactive substance used to formulate the active ingredient in Chantix into a tablet or pill, not the result of a defect in any manufacturing process. As set forth below, because FDA specifically approved the excipient Pfizer used to make Chantix when FDA approved Pfizer's NDA, and Pfizer could not have changed the Chantix formulation (including the excipient) without FDA's prior approval, Pfizer has a clear preemption defense, and Plaintiffs cannot prevail on their sole remaining cGMP violation claims.

When Pfizer submitted the Chantix NDA to FDA, that submission included extensive information about Chantix's chemistry, manufacture, and control, including a description of all components used to manufacture the drug product (the active pharmaceutical ingredient and excipients), their function, and testing performed by Pfizer – *and including the process controls Pfizer established for manufacturing Chantix*. 21 C.F.R. §§ 314.50(d)(1)(i) & (ii). When FDA

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approved Chantix, it determined that the drug product, including the excipients and Pfizer's processes to make Chantix, were safe and effective for use in patients. 21 C.F.R. § 314.125(b).

Once FDA approved Chantix, Pfizer could not make any "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved NDA" without submitting a supplement and obtaining prior FDA approval. 21 C.F.R. § 314.70(b)(2)(i); *see also* 21 C.F.R. § 314.70(b)(1) (requiring a supplement for changes in production processes and quality controls); 21 C.F.R. § 314.70(b)(3) ("The applicant must obtain approval of a supplement from FDA prior to distribution of a drug product made using a change under paragraph (b) of this section."). As such, the appropriateness of the excipient used by Pfizer is a determination made by FDA, which Plaintiffs cannot "privately enforce . . ." *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997).

In the parties' meet and confers, Pfizer informed Plaintiffs of its position on the legal significance of the excipient as the source of the nitrosamine in Chantix. Pfizer also agreed to produce other documents that may be relevant to the preemption issue. (*See* Exhibit A.) Pfizer told Plaintiffs that it was willing to meet and confer further after producing these documents and the Plaintiffs' review to explore whether they still believe additional discovery is necessary on the preemption issue. (*Id.*; *see also* Exhibit B.) Pfizer also told Plaintiffs that it intended to propose to the Court a scheduling order for limited discovery and early dispositive motion practice on preemption, but that it was waiting for the Court to rule on the remainder of Pfizer's Motion to Dismiss, as is customary under the Federal Rules of Civil Procedure. (*See id.*)

If the Court is inclined to set a scheduling conference, Pfizer welcomes the opportunity to discuss its scheduling proposal in more detail, which Pfizer believes will significantly streamline the litigation, conserve resources, and prevent waste where the resolution of those issues could be dispositive, as other MDL courts have done. *See, e.g.*, *In re Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) Prods. Liab. Litig.*, MDL No. 3094, 2024 WL 4520117, at *1 (E.D. Pa. Oct. 17, 2024); *In re Incretin Mimetics Prods. Liab. Litig.*, No. 13-MD-2452, ECF Nos. 325, 567 (S.D. Cal. Feb. 18, 2014); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, ECF No. 875 (Pretrial Order No. 30) (S.D. Fla. June 18, 2020); *In re Viagra (Sildenafil Citrate) Prods. Liab. Litig.*, No. 16-MD-02691, ECF No. 102 (N.D. Cal. Sept. 26, 2016).

Respectfully,

/s/ Loren H. Brown
DLA PIPER LLP (US)
1251 Avenue of the Americas, 28th Floor
New York, NY 10020-1104
T: 212-335-4846
loren.brown@us.dlapiper.com

Counsel for Defendant Pfizer Inc.

cc: Counsel of Record (via ECF)

The Court is in receipt of Plaintiffs' letter outlining certain discovery disputes between the parties (Dkt. #73), and Defendant's response (Dkt. #74). The Court DENIES the request, except as stated herein. By way of background, the Court initially granted a stay of discovery by endorsement dated April 17, 2023, in light of Defendant's contemplated motion to dismiss. (Dkt. #35). The Court's Opinion and Order granting in part and denying in part the motion to dismiss was issued on May 28, 2024. (Dkt. #58). However, in light of its order for supplemental briefing on issues concerning pre-suit notice requirements and the economic loss doctrine, the Court did not lift the stay on discovery, and did not contemplate doing so until it had resolved these remaining issues. Submission of the parties' supplemental briefing was completed in late September 2024, and the Court will review those materials in due course. After resolution of the remaining issues, the Court will discuss with the parties an appropriate discovery schedule. Among other things, the Court believes that the parties would benefit from knowing precisely what claims remain in the case and tailoring their discovery requests accordingly.

The Court understands that Defendant has produced certain documents, and has committed to producing certain other documents, including in particular the New Drug Application ("NDA") and the regulatory file for Chantix. (Dkt. #74 at 2). The Court expects that Defendant will abide by those production commitments, but it will not otherwise require the parties to "finalize document custodians and search terms, and to begin rolling productions of responsive documents and information[,]" as Plaintiffs request. (Dkt. #73 at 1). In so doing, however, the Court takes no position on Defendant's proposals for targeted discovery and/or early summary judgment practice on the issue of preemption.

The Clerk of Court is directed to terminate the motion at docket entry 73.

Dated: December 23, 2024
New York, New York

SO ORDERED.

Katherine Polk Failla

HON. KATHERINE POLK FAILLA
UNITED STATES DISTRICT JUDGE